shapeable portion such that the length of the shapeable portion can be adjusted by an operator of the medical probe.

REMARKS

This paper is responsive to the Final Office Action mailed February 24, 2003. Presently, claims 1-20 and 22-24 stand rejected. Claim 21 has been allowed. Applicants respectfully request reconsideration of the claim rejections in view of the remarks provided hereinafter, and the amendments to the claims as provided above.

Claims 1 was rejected under 35 USC §112, second paragraph, for lack of antecedent basis. Claim 1 has been amended as provided above in a manner that is believed to overcome this rejection.

Claims 1-20 and 22-24 were rejected under 35 USC §102(e) as being anticipated by Merideth (U.S. Patent No. 6,164,277) or Salmon et al. (U.S. Patent No. 5,503,155).

The Merideth patent discloses an intubation stylet that is used to detect air movement in the trachea during endotracheal intubation. The Merideth intubation stylet includes a guide member 12, a control handle 14, a signal processing unit 16, a transducer 17 located at the distal end of the guide member, and a cable 20 that operatively connects the transducer to the signal processing unit (Fig. 1).

Claim 1 of the present application, as amended, is directed to a medical probe for detecting the flow of *blood* within a bodily passage. The transducer head includes an ultrasonic transducer adapted for generating signals in response to the flow of *blood* within the bodily passage. The transducer head of claim 1 also includes an encasing material surrounding the ultrasonic transducer. A plastically deformable cannula extends proximally from adjacent the distal end of the device.

As stated, the Merideth device is used for detecting the passage of air in an airway. It is not, and apparently cannot, be used for detecting the flow of blood in a bodily passageway. In addition, the transducer head of claim 1 includes an encasing material surrounding the transducer. An example of a suitable encasing material is an epoxy material, as claimed in dependent claim 6. No such encasing material is provided in the Merideth device. Furthermore, the probe of claim 1 comprises a plastically deformable shapeable portion. The Merideth device discloses a flexible guide member (Col. 5, lines 41-60). Merideth does state, in passing, that the guide member may optionally be made of a malleable material, as pointed out by the Examiner in the Office Action. However, it does not teach the use of a plastically deformable cannula as claimed.

Claim 5 of the present application have been cancelled, and its limitations have been incorporated into claim 1. The dependent claims also include limitations not disclosed in Merideth. For example, dependent claim 3 includes the limitation that the transducer head is moveable relative to the distal end of the shapeable portion, and claim 4 (dependent on claim 3) includes the limitation that the transducer head is adapted to at least partially reside within the shapeable portion, and is at least partially extendable from the distal end thereof. Neither of these features is taught in Merideth. Dependent claim 6 has been amended to change its dependency to claim 1. This claim includes the limitation that the encasing material includes an epoxy material, which is also not disclosed in Merideth.

In addition to the foregoing, dependent claims 7 and 8 describe the orientation of the ultrasonic transducer with respect to the longitudinal axis of the medical probe. Claim 9 states that the electrical conductor comprises a first and second wire attached to the

transducer. Claim 10 (dependent on claim 9) states that the first and second wires include shapeable wire. Claim 11 states that the shapeable portion comprises a malleable core wire, wherein the electrical conductor is located thereabout, and claim 12 (dependent on claim 11) states that electrical conductor comprises a first and second wire helically wrapped about the malleable core wire. Claims 13-15 teach a probe wherein a transducer head includes a plurality of ultrasonic transducers. None of these limitations is disclosed in the Merideth patent.

Independent claim 16 has also been amended as provided above. As amended, the medical probe of claim 16 detects the flow of *blood* within a bodily passage. The probe includes, among other things, a transducer head, an electrical conductor adapted to generate and process Doppler signals in response to blood flow within a bodily passage, a handle portion, an outer sheath connected to the handle portion that at least partially houses the electrical conductor, wherein the distal portion of the outer sheath extends distally from the handle portion and at least partially comprises a plastically deformable shapeable portion, and wherein the handle portion is slidable relative to the shapeable portion such that the length of the shapeable portion can be adjusted by an operator of the medical probe. Prior to its incorporation into claim 16, this latter limitation was originally present in dependent claim 19. Claim 19 has now been cancelled.

As stated above with reference to independent claim 1, the claimed device is distinguishable from the Merideth device, since Merideth is an intubation stylet for detecting the passage of air in an airway during an intubation procedure. Merideth does not teach a device for detecting bodily liquids, such as blood. In addition, Merideth does not disclose, among others, a conductor adapted to generate signals in response to blood flow, nor does it teach a slidable handle.

The Salmon et al reference discloses a drive cable for rotating an ultrasonic transducer for use in intravascular imaging of blood vessel lesions. The drive cable 10 includes a flexible counter-wound coil 12 comprising an outer coil 14 and an inner coil 16. A support tube 18 is received within a central lumen 20 of inner coil 12, and a pair of twisted electrically insulated wires 22 is received within a lumen of tube 18. An ultrasonic transducer 42 is secured at the distal end 44 of the drive cable.

The Salmon reference does not teach a transducer head including an encasing material surrounding the ultrasonic transducer. In addition, the Salon reference does not appear to teach a medical probe for detecting flow of blood, nor does it include a transducer adapted for generating signals in response to blood flow. Rather, the transducer of Salmon is used for imaging purposes.

The dependent claims also include limitations not disclosed in Merideth. For example, dependent claim 3 includes the limitation that the transducer head is moveable relative to the distal end of the shapeable portion, and claim 4 (dependent on claim 3) includes the limitation that the transducer head is adapted to at least partially reside within the shapeable portion, and is at least partially extendable from the distal end thereof. Neither of these features is taught in Salmon. Dependent claim 6 includes the limitation that the encasing material includes an epoxy material, which is also not disclosed in Merideth. Dependent claims 7 and 8 describe the orientation of the ultrasonic transducer with respect to the longitudinal axis of the medical probe. Claim 11 states that the shapeable portion comprises a malleable core wire, wherein the electrical conductor is located thereabout, and claim 12 (dependent on claim 11) states that electrical conductor comprises a first and second wire helically wrapped about the malleable core wire.

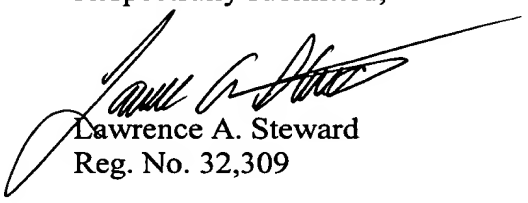
Claims 13-15 teach a probe wherein a transducer head includes a plurality of ultrasonic transducers. These limitations are not disclosed in the Salmon patent.

Independent claim 16, as amended, is also not anticipated by Salmon. In addition to the comments provided above, Salmon does not include a handle portion in general, nor does it include a slidable handle portion having an adjustable length.

Based on the foregoing, Applicants respectfully request that all remaining claims, namely claims 1-4, 6-18 and 20-24, are now in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. Although the pending claims are under final rejection, Applicants respectfully request that this amendment be entered into the case. All of the claim amendments resulted from incorporating limitations from existing claims into other claims. Thus, the amendments should not necessitate a new search, nor do they introduce any new issues that were not already in the case. Alternatively, Applicants respectfully request that the finality of the previous rejection be withdrawn. The final Office Action did not include any reference to independent claim 16, nor did it provide any explanation for the Examiner's conclusion that the cited references, newly-cited for the first time in the final Office Action, anticipated this independent claim. In addition, the final Office Action did not provide any reasons why the dependent claims are anticipated over either of these newly-cited references. Clearly, the references do not anticipate these dependent claims, for the reasons discussed above.

If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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Marked up copy of claims:

1. (Twice Amended) A medical probe for detecting flow of [fluid] blood within a bodily passage, the probe having a distal end and comprising:

a transducer head that includes an ultrasonic transducer[s] adjacent the distal end of the probe, the ultrasonic transducer[s] adapted for generating signals in response to [fluid] blood flow within said bodily passage, the transducer head including an encasing material surrounding the ultrasonic transducer;

an electrical conductor having a first end and a second end, the first end being operatively connected to the ultrasonic transducer, and the second end being connectable to an external source unit for processing flow-responsive signals; and

a shapeable portion extending proximally from adjacent the distal end, said shapeable portion being a plastically deformable cannula.

6. (Amended) The medical probe of claim [5] 1, wherein the encasing material includes an epoxy material.

16. (Twice Amended) A medical probe for detecting flow of [fluid] blood within a bodily passage, the probe [having a longitudinal axis and] comprising:

a transducer head that includes an ultrasonic transducer having a first operative surface;

an electrical conductor[,] comprising two wires, each wire having a first end and a second end, the first ends being operatively connected to the ultrasonic transducer, and the second ends being connectable to an external source unit adapted to generate and process Doppler signals in response to blood flow within the bodily passage;

a handle portion;

an outer sheath connected to the handle portion and at least partially [houses] housing the electrical conductor, the distal portion of the outer sheath[, which extends] extending distally from the handle portion[,] and at least partially comprising a shapeable portion [with the shapeable portion] having a distal end, the shapeable portion being plastically deformable such that it retains a deformed shape as the probe is manipulated within the bodily passage; the transducer head being affixed about the distal end of the

shapeable portion; said handle portion slidable relative to the shapeable portion such that the length of the shapeable portion can be adjusted by an operator of the medical probe.